

ASSESSMENT OF HEALTH MANPOWER PILOT PROJECT (HMPP #171)
Shasta-Diablo Site
February 5, 2008

Purpose: To evaluate the progress of the project in meeting its stated objectives and in complying with program statutes and regulations. This is a site visit to the first participating clinic.

Method: Interviews with HWPP #171 Administrative Team, Trainees and Trainers; Review of Curriculum/Protocols, Review of Medical Records Abstractions and Patient Satisfaction Summary.

xxxx This section has been redacted. xxxx

HWPP #171 - Project Director
Jennifer Dunn, JD

Evaluation Team

OSHPD

Health Workforce Pilot Projects Program
Gloria J. Robertson

Healing Arts Boards:

Board of Registered Nursing
Louise Bailey, RN
California Medical Board
Kelly Nelson & Laurie Gregg, MD

Technical Consultants

UCD FNP/PA Program
Betty Ingels, PhD, FNP, PA-C

Related Professional Associations

American College of OB-GYN, District IX –CA
Laurie Gregg, MD
Assoc. of Reproductive Health Professionals
Rivka Gordon, PA-C, MHS

HWPP #171 TEAM

Jennifer Dunn, JD

*Past Project Director, Currently- Legal
Compliance Law and Policy Advisor

Molly Battistelli

*Project Director

Erin Schultz, JD

Legal Compliance – Law and Policy Fellow-Legal
Research Assistant

Diana Taylor, RN, PhD

Principal Investigator

Kristin Nobel, MPH

Evaluator

Julie Jura

Research Coordinator

Phyllis Schoenwald, PA

Shasta Diablo Clinic VP Medical Services

Lily Spitz, JD

Chief Legal Counsel, Planned Parenthood
Affiliates of California

Marsha Stamhill.

Planned Parenthood Affiliates of California

*** Notification of Change in HWPP #171 Staff Responsibilities.**

I. Pre-Assessment Team Conference Discussion:
OSHDP Staff and Evaluation Team

Currently the HWPP #171 has participation contracts with three training-clinical sites. They are located in Concord, San Diego/Riverside and Los Angeles, California. The other sites will be initiated in 2008. Their locations will be in Northern California and the Central Valley. The Shasta-Diablo Clinic is the first site to come aboard. This particular assessment is crucial, as UCSF, the sponsor has requested an extension of time to continue the project proposal. Their approval to participate expires March 31, 2008. I would need to provide Dr. Carlisle with information on the status of the Project for his determination of extension approval.

Other Matters of the Day:

- OSHPD has agreed, with the sponsor, to certain confidentiality protocols for this site visit. The Clinic and Sponsor are concerned about participant confidentiality. Thus, the site will have a HIPPA agreement form for you to review and sign. OSHPD legal has already reviewed the form and consented for our use today (2.05.08).
- Regarding Clinical Records – HWPP received a preliminary listing of records (per codification) pertaining to this site. HWPP Program Manager asked that they make available abstractions reflecting 51% of the listing for the Teams' review. HWPP has on file the number of patients who have participated in the Shasta-Diablo site. The listing that was used during the visit remained with the site after the conclusion of our visit.
- With regard to the validity of the data reflected on the abstracted records summary, the Project Staff by making available the information certified that the data pertains to the HWPP#171 Project, at Shasta-Diablo Clinic (participating trainees, trainers and consenting patients).
- Lunch – UCSF ordered the lunch for all site visit participants. Receipts for the HWPP Team were sent by e-mail to OSHPD-HWPP for distribution.

II. Welcome & Introductions -All Participants

III. Review of Project – Project Status -UCSF

Persons participating in the site visit assessment are listed above. The Medical Director for Shasta Diablo, trainer/preceptor and trainees were available for the introductions. UCSF provided the Team with an update to the project. They presented the project application that is labeled as approved by OSHPD 3/21/07, Updates submitted on 2/05/08. The addendums to the approved application were integrated into the appropriate pages in the update.

Updates include - change in sponsor organizational chart-staff responsibilities, resumes for the changed staffing, training agreement, consent form, curriculum overview, informed consent form for patients, phase one and phase two experimental subjects bill of rights, and an update to the advisory board.

Molly Battistelli, Project Director, reiterated their hopes of having 50-60 Trainees overall in the seven sites.

The curriculum –APC Curriculum, Supplemental Reader and the Early Abortion Training workbook were presented to the Team for their perusal. OSHPD-HWPP has a copy on file.

Q1. The OSHPD abstract list your funding source and levels per the submission of the approved application. Have you secured any funding since the initial phase (per the abstract listing), if so what is source and level of that funding and timeframe of the funding?

Response

The UCSF-APC project has received an anonymous donation in the amount of \$3.5 million dollars that will cover the planned three year period. The expected use of the money per year is attached. The funding source and levels on the abstract reflect the proposals initial efforts.

Q2. There was some discussion about having the sites raise money for the Project.

Response

Not all sites are raising money for the project. However, sites are encouraged to raise money to use in backfilling APC positions while the chosen Trainees are participating in HWPP #171. Sites are also providing some in-kind services.

Q3. The application indicated that there was an advisory board to the project. Could you give us information regarding their input to the project?

Response

Dr. Diana Taylor is now chairing the Advisory Committee (replacement for Dr. Felecia Stewart, deceased). The Advisory Board has a sub-committee on safety and monitoring. That subcommittee has provided direction to the project in the area of quality assurance protocols, clinical practice standards and patient safeguards. It was suggested that the various sites obtain a private firm for the Institutional Review Board (IRB's). Kaiser will use their internal IRB for project participation purposes. Initially, the Advisory Board provided input into the design of the HWPP #171 proposal. The Advisory Board suggested that participating sites have consent forms translated in Spanish and that all forms be at an appropriate reading level for the Clinic population.

HWPP observation- Several of the HWPP #171 participants serve on the Advisory Board, e.g. UCSF and Clinic representations.

IV. Site Visit Protocols – Review and Discussion

All Participants

Jennifer Dunn – Molly Battistelli discussed the HIPPA confidentiality forms, site sensitivity to Project participants and participating patients. Confidentiality forms were provided to each member of the Evaluation Team to review and sign. Project Staff who were assigned to oversee the development of the clinical records abstractions also signed certification forms to verify that the data pertains to the HWPP #171 project.

OSHPD-HWPP Program Administrator indicated that the Evaluation Team represents an interdisciplinary approach and that all present would participate in the various site visit aspects, e.g. Interviews, review of protocols, and review of clinical records abstractions.

V. **Assessment of Operations**

Administrative Records, Interview(s) with Project Participants, Clinical Records – Aggregate Data & Medical Records Data Verification

Interviews with Trainees and Preceptor: There are five APC participants at this site: four Nurse Practitioners and one Nurse Midwife. Two of the trainees have completed their didactic and clinical training and are now in the E/U phase. Originally, there were six candidates. One candidate was unable to participate in HWPP #171 due to personal and clinic scheduling. Shasta-Diablo hopes to fill the vacant sixth space with an APC-Physician Assistant later this year.

Trainee-680 (T-680):

Employment History: This APC has 14 years of experience in women's health service. T-680 began her career as a volunteer at Planned Parenthood clinics and enjoyed the introduction of providing women's health care services observed during her volunteer period. T-680 trained to become an RN-NP women's health specialist. Her practice has included pre opt for 2nd trimester examines/procedures, IUD placement experience, being present during the patents consultation regarding miscarriage management. T-680 is a member of the UCSF Advisory Board.

New Role: As a Trainee in this Extended Capacity: T-680 has completed the requisite 100 procedures, 40 during training and 60 during the clinical phase. T-680 feels comfortable in her new role and feels that the training time allocated was flexible enough for her to reach the comfort level. She has experienced the feel of an empty uterus, the change in process and feel of IUD placement to the aspiration processes. The preceptor is always on site during the training period. That backup is security for the trainee.

T-680 indicated that the staff at Shasta Diablo is responding favorably to her changing role.

Clinical Experience: The screening coordinator in coordination with the preceptor assigns patients for her training. The screening coordinator is the individual who interviews the patient and obtain the consenting form. The preceptor assigns the APC to be present for training. She is scheduled to be at the clinic on those days where abortions are performed and per the preceptor's perusal. The comfort level increased between the twenty to forty performances of procedures mark. The Trainee is still becoming more confident /comfortable after forty procedures.

T-680 indicates and Project staff confirms that training is one on-to-one level that is one trainee to one preceptor. T-680 may provide the local anesthesia, order certain medications to prevent infection and birth control pills if requested. They do the pre opt. T-680 has not experienced any complications. T-680 understands that one patient may have required follow-up attention, but the patient sought assistance at another clinic for the attention (antibiotic inquiry).

A Clinic Patient Coordinator screens consenting patients. Trainees at Shasta Diablo do not, as part of their role screen patients for participation or obtain consent forms. T-680 abides by the standard procedures template of the HWPP #171 project for aspiration abortions. T-680 may

perform up to 7-11 procedures in a day. Status of patients for her training ranged with minimum of seven weeks to eleven weeks gestation.

Qualms during training: risk of perforations of uterus, learning to recognize...what a complication is, learning the various techniques/technical aspects of procedures.

Patient Follow-up. The trainees have not experienced any follow-up after care. Generally, at Shasta Diablo, a clinic RN takes the call---the Medical Director takes the call when required. Follow-up to patients is generally initiated forty-eight to seventy-two hours after discharge. T-680 made follow-up calls during the training phase-1st forty procedures. The response rate was 55% for the APC and 35% for the physician.

Project staff indicated that personal integrity, personal interest, those with certain experiences, and geographic location are characteristics sought out for participation in project at Shasta Diablo.

Records Management- The signed patient consent forms are kept in an administrative area of the Clinic- in a locked clinic file and are password protected. The on-site Research Coordinator keeps APC patient logs. This individual charts and abstract data for the Shasta Diablo clinic site.

Relationship of the Employment/Utilization Experience to the Didactic/Clinical Rotation Course and Expected Project Outcomes – T-680 indicates that she had the opportunity to observe an ectopic pregnancy procedure.

T-11 Preceptor

Overview of Present Position: T-11 has been a physician for approximately twenty-six years; Specialty in HPV, Abortions Services, Obstetrics-Gynecology, a member of the Federation of Medical Directors. He enjoys teaching, consulting and precepting for residents from the Martinez County.

Pilot Project Role: T-11 is humble, philosophical and supportive of the project. He uses a conservative approach in choosing the Shasta-Diablo trainees and is protective of the trainee. T-11 preceptorship is a one-on-one role with the APC. He is very comfortable in this role. T-11 is on site and present when the APC is scheduled for work. There is a back-up preceptor system in the facility. T-11 indicates that there are benefits for training APC's for this type of project, it: increases the workforce for a greater access to women's health care, provides a community service, shortens the social issues surrounding access to care, and is a less cost of time consumed by the practitioner and the client in terms of service access. Planned Parenthood has several clinics within the geographic area. If trained APC's were available in these clinics, it would strengthen the community services to the population, shorten commuter time to service, shorten the social issues regarding obtain service, less cost of time. The use of APC's would increase the workforce. It would provide a good system for staff rotations.

Trainee Evaluation: APC's chosen were exceptional students, those who excel. They are the exceptional practitioners. The forty procedures mark is the standard confidence level. The

Trainee still lacks confidence but is comfortable with the M.D. as a backup. Patient stages for the introduction of the APC are characterized as early at 4.5 – 5 weeks; normal range at 5-7 weeks to 12 weeks of gestation. However, APC's are entered into the procedures based on techniques. Not in terms of gestation.

The preceptor has no problems with saying no...to the advancement of the practitioner or to not allow a practitioner to participate in the training when warranted.

Clinical: Complications – where a second aspiration procedure is warranted, where tissue may have been retained or --- where there is perforation of the area.

Q (1). Do you simulate complications during the training phases for the APC?

Response by T-11: It would not be helpful to simulate complications. Complications vs. difficult procedures are introduced to the Trainee but in stages so as to make the trainee feel empowered...but not to pass their comfort level.

It is important that the Trainee know their limitations. The APC's differ in terms of strength and weaknesses. For example, T-680 – Strengths took a bit longer in some stages...but that is OK. It strengthens the APC and the APC can do later procedures. T-680 weakness - could have used more experience. But that is a matter of time.

This APC's have better hands than expected. They are learning communication skills with the client in proper pain management; she receives validation from other physicians in rotation (residents).

The APC's do not handle the paperwork, e.g. observed performance logs, procedures logs, and patient complication tracking or trainee clinical schedules.

Reporting Procedures/Shared Information: Comments regarding program enhancements: They could use more room in the recovery area. They could use more clinical coordinators to assist in screening the patients for procedures.

Q (2): Are their standardized procedures for the APC in this project.

Response: Yes, the Clinic has standardized procedures for the APC's. These protocols govern APC during the training and employment-utilization phases of the project. Standardized procedures are the legal mechanisms for APC's to perform functions which otherwise might be considered the practice of medicine.

Trainee 543:

Employment History: T-543 became a Registered Nurse in 1971. She began working with the Planned Parenthood Clinics in 1988-1992, and became a Nurse Practitioner in 1993.

New Role: As a Trainee in this Extended Capacity: T-543 is very comfortable in her new role - medically, emotionally and academically. She is excited by providing access to care to

women. She enjoys being on the cutting edge for her profession. She indicates that during their training phase they were given open book examinations. She enjoyed this method of testing in that she was able to learn and retain more.

Clinical Experience: T-543 indicates that her support/validation of her training comes when a second physician who is not the preceptor signs off on her procedures. The signature represents that she performed/completed the procedure as required and at the competency level.

Relationship of the Employment/Utilization Experience to the Didactic/Clinical Rotation Course and Expected Project Outcomes: Today, February 5, 2008, is T-543's first day for the employment –utilizations stage and she is very excited about her day. Her interview was late in the day so that she could complete the assigned patient procedures.

Assessment of the Administrative Component:

Regulation: (Section 92304) Sponsor Information:

Regulation: (Section 92312) Modifications.

The sponsor provided the team with the 'updated application' for our review. OSHPD-HWPP has a copy for file. The update did indicate the changes in project staffing, e.g. new project director-Ms. Molly Battistelli. Ms. Jennifer Dunn will retain position in Project Legal Compliance. The funding source as enumerated earlier is from an anonymous donor in the amount of \$3.5 million dollars to cover a three-year period. A budget revision was added to the update. A new organizational chart for the HWPP #171 was also included in the update.

Curriculum includes a syllabus. It seemed thorough and adequate for scope of practice of this project.

In summary, the curriculum included the following:

Orientation: counseling, pre-abortion evaluations, educations and pain control, aspiration abortions and procedures, post abortion care; managing problems, medications for abortion, early pregnancy loss, office practice-quality health and safety evaluations, procedures log, daily admissions, --- perform assessment /incident reporting form, patient follow-up, survey

Evaluations: Instructions for didactic and clinical – pre/post surveys, practice log - trainee patient data, procedures time –daily assessment of trainee and trainer, observed performance assessment – list, beginner's demonstration for competency, abortion incident report form and patient survey forms.

We did not see a contract or memorandum of understating with a general acute hospital. However, the information is documented in the protocols.

Regulation: (92305), (92311). Trainee Information.

The sponsor and team discussed the delegation of services agreement for the trainees. There were no physician assistants in the chosen trainee group. The sponsor was guarded about the public disclosure of information. The team signed the Clinics HIPPA confidentiality form.

Regulation: (92306). Curriculum.

Curriculum includes a syllabus. It seemed thorough and adequate for scope of practice of this project. Criteria as listed in regulations were met.

Regulation: (92308) Monitoring

One of the Evaluation Team members indicated that she reviewed the quality assurance information regarding protecting patient's safety. Evaluation Team did not see the Trainees competency log or the Supervisor's log depicting fulfillment of role and responsibilities. These areas were discussed and verbally agreed that there is monitoring for patient safety.

Regulation: 92309. Informed Consent

The Sponsor discussed the method used to apprise the patient of the pilot project and to obtain informed consent to participate in the project. The research coordinator for the Clinic performs this function.

Regulation: (92310) Costs.

The five-year proforma was reviewed and discussed. It is located in the updated application. We still need to obtain a better handle on the cost of the training component. We have the budget for the training and clinical aspects....butis this the actual cost of the components. In that the Clinic is raising money to backfill Trainee positions, we will want to later inquire about this impact. (e.g., What is the cost to backfill? We did not discuss this to that extent.)

Employment/Utilization Component:

Regulation: (92101) Minimum Standards.

Evaluation Team has indicated that the minimum standards listed were met. Note: OSHPD-HWPP has a listing of the trainees and trainers for the contracted sites. The team was introduced to two trainees and the preceptor for Shasta-Diablo.

Regulation: (92308) Monitoring.

The Evaluation Team has indicated that the criteria as listed for this regulation section were met. Trainee competency, supervisor fulfillment of role and responsibilities and site compliance with criteria was discussed with the sponsor, Trainee, and Preceptor.

Regulation: 92309. Informed Consent.

The plan used to obtain prior informed consent from patients to be treated by trainees or those legally able to give informed consent for the patients was discussed by the sponsor and project staff of the clinic.

The sponsor and the preceptor (T-11) discussed the role and the status of the Trainees, including their readiness. The sponsor and the preceptor discussed the ability of the proposed patient to decline participation. They indicated that approximately five to ten percent decline. The consent form is included in the application. The Research Coordinators signed and presented their certification for the data summaries made available to the team. The Sponsor described in the overall discussion that their Advisory Body recommended that the forms be translated in Spanish.

Provision for obtaining the informed consent. The Evaluation Team did not see any consent forms with signature affixed. Not seen due to confidentiality.

Regulation: 92310. Costs.

Cost under this component was not discussed. The Team per the HWPP Staff will obtain this information later. The information in the application reflects the expectations.

Regulation: 92311. Trainee Information.

The public disclosure of the Trainee or preceptor is by codification, e.g. T-11 for Preceptor and T-680 or T-543 for the Trainees interviewed. The other trainees who have not completed the training phase are listed at OSHPD-HWPP in codification format.

Regulation: 92603. Site Visits.

The Evaluation Team believes that the project at Shasta Diablo is complying with the approved application. The Team did hold interviews with two of the trainees and the Preceptor. The team did not interview any patients...confidentiality of the Clinic. The Evaluation was composed of a Interdisciplinary Team representing (1) Healing Art Boards—Representatives of the Board of Registered Nursing and the Medical Board of California, (2) Professional Organizations- Representatives of the American College of OB-GYN, District IX –CA and the Association of Reproductive Health Professionals, and Other State Bodies- A Technical Consultant from the University of California Family Nurse Practitioner\Physician Assistant Program.

Review of Data:

Patient Satisfaction Summaries: OSHPD-HWPP was given a copy of the survey form. The sponsor presented a summary of their findings to the team. One question required some clarification –wording structure.

The patient satisfaction forms were made available to the patient/client during post recovery--- in the recovery room area –to those patients who had a first trimester aspiration abortion procedure. They had an option of reviewing a form in either English or Spanish. A summary of comments are as follows:

- *Overall Patient Satisfaction:* All patients seen by the APC reported an average rate of satisfaction above 9.0 on a scale of 0-10 where zero = Completely Unsatisfied and 10 = completely satisfied. MD (comparison group) patient overall rating was 9.3
- *How Well Patient Felt She was Treated by Provider:* Patient rated their perception of how well they felt they were treated at 4.9 on a scale of 1-5 where one= Poor, 2= fair, three = Good, four= Very Good and five = Excellent. There were no negative comments regarding treatment provided by an APC but one negative comment directly related to the medical doctor treatment. MD (comparison group) patient overall rating was 4.7.
- *Would Patient Recommend the Clinic:* Nearly all patients would definitely recommend the clinic to friends and family. The few patients who would “maybe” recommend the clinic had complaints about the long waiting times or the lack of choice about pain management (preferred conscious sedation to oral pain medication). (On a scale of 100% they reported

93.9% = Yes, definitely would recommend and 6.1% Maybe they would recommend.). MD (comparison group) patient overall rating was 94.1 = Yes, definitely would recommend and 5.9% Maybe they would recommend).

- *Procedure Satisfaction and Patient's Expectations:* Of the total patients in this first quarter report, two-thirds of the patients (seen by APC's and MD's) reported their experience as better than expected and only two patients reported the experience as worse than expected. In this "worse than expected" group, the one patient seen by the APC had expected conscious sedation rather than the oral pain medication that she received. The one patient seen by the medical doctor felt that she was treated disrespectfully. Seventy percent of the medical doctors rated their experience as better than expected compared with 54% of the APC patients. Since the APC patients overall satisfaction was nearly identical to that of patients seen by the medical doctors, this difference in expectations may be due to the more thorough consent process by the APC patients.
- *Pain and Anxiety During this Procedure:* Data on patient's experiences with pain during the procedure as well as anxiety regarding the procedure are also collected as part of the assessment of women's satisfaction with care. Women receiving first trimester abortions at this clinic during the first quarter of data collection report moderate pain levels for the 3-5 minute abortion procedure with no clinically significant differences between the APC and the medical doctor's procedures. In this quarter, women reported moderate anxiety (mean = 6.2 on a scale of zero= not nervous and 10= very nervous) associated with the abortion procedure with no clinically significant difference between the APC and the medical doctor providers.

Members of the Team reviewed abstraction records for the APC column. We were unable to review all records requested due to time constraints.

Clinical records abstractions showed patient demographics, reimbursement types such as Medical. Regarding the outcomes from procedure by the APC, there were no contraindications (adverse reactions, incidents, and occurrences) reported.

Follow-Up Interviews with participating #171 Shasta Diablo clients/patients: The response rate for patients follow-up was 55 percent activity. The team feels that this is low follow-up percentage for a study. There did not appear to be any face-to-face follow-up with patients. Perhaps the APC's and the Clinic personnel could take a more active role in following up with patients post the procedures recovery stage. Perhaps a follow-up session could be scheduled within two weeks post procedure.

"Should there be a commitment on the part of the participating client/patient regarding follow-up post procedure?" (Evaluation team ending question/comment).